DEPARTMENT OF THE ARMY
HEADQUARTERS, EIGHTEENTH MEDICAL COMMAND
UNIT #15281
APO AP 96205-0054

REPLY TO
ATTENTION OF:

EAMC (40) 30 May 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Integrated Healthcare Organization Policy # 20 – Point of Care Testing (Waived Testing)

1. **PURPOSE:** This program will establish policy, responsibility and procedural implementation and management for Point of Care Testing (POCT) within the Integrated Healthcare Organization (IHO).

2. **APPLICABILITY:** This program is applicable to all sites performing waived testing as defined by the Federal system of "waived", "moderate complexity", "high complexity" and "provider-performed microscopy". Although the College of American Pathologists (CAP) definition of point of care testing (POCT) does not include limited service laboratories with a fixed, dedicated testing space, in the military, this policy does apply to remote sites with fixed laboratory facilities that are currently registered with the Clinical Laboratory Improvement Program Office (CLIPO) under the Office of Clinical Laboratory Affairs (OCLA) at the Armed Forces Institute of Pathology (AFIP) in Washington, DC that perform waived testing. It is also applicable to all analytical patient testing activities provided in the institution but performed outside of the physical facilities of the clinical laboratories. All sites performing waived testing must be in compliance with the CAP "Point of Care Testing Checklist" guidelines and are inspected by CAP every two years.

3. **RESPONSIBILITIES:**

a. 18th MEDCOM PATHOLOGY CONSULTANT (Chief, Department of Pathology, 121st General Hospital) will:

(1) Serve as the Pathology Consultant, for the IHO POCT program. He/She will exercise authority and jurisdiction over waived testing performed at all IHO sites.

(2) Designate a POCT Coordinator as the technical consultant to the POCT supervisors at testing site.

(3) Establish the POCT policy and procedures and enforce compliance with the same.

(4) Serve as the approving authority for sites requesting permission to perform point of care test procedures.

b. POCT Coordinator will:

(1) Serve as the technical designee of the 18th MEDCOM Pathology Consultant to ensure centralized coordination of documentation/records for the POCT program. The POCT Coordinator will serve as the point of contact for all POCT supervisors within the IHO regarding issues related to waived test procedures.

(2) Assist the sites with an appropriate selection of test methodology.

(3) Verify test procedures and provide written instructions for performance of waived test procedures (SOP's).

(4) Assist POCT sites in enrollment and participation in proficiency testing programs. Administer internal proficiency testing and monitor both internal and external programs commensurate with services offered.

(5) Establish a quality control program appropriate for each test procedure. Receive, tabulate and aggregate Quality Control (QC) data from all IHO POCT sites.

(6) Coordinate with POCT supervisors in resolving technical problems and ensure that remedial actions are taken and patient test results are not reported until all corrective actions are taken and functioning properly.

(7) Training:

(a) Identify training needs and coordinate training of all POCT personnel by working closely with POCT supervisors.

(b) Maintain all training documentation in the Department of Pathology.

(c) Train the POCT supervisors as part of "train the trainer" program (See POCT program for details).

(8) Report the status of POCT to the 18th MEDCOM Pathology Consultant and Chief, Department of Pathology, 121st General Hospital. POCT performance improvement initiatives are developed, implemented and assessed by the Department of Pathology Performance Improvement Committee.

(9) Inspect IHO POCT sites in accordance with Joint Commission on Accreditation of Healthcare Organization (JCAHO) and College of American Pathologists (CAP) standards. The following will be evaluated:

(a) POCT Supervisor (Duty Appointment Orders).

(b) Supervision and Training of POCT Personnel.

(c) POCT personnel roster.

(d) Competency Verification/Color Vision Test of POCT Personnel.

(e) Procedural Manuals (SOP's) (Reading & Understanding) w/sign in roster.

(f) Specimen Handling.

(g) Instruments and Equipment.

(h) Reporting of results.

(i) Controls and Reagents (Documentation).

(j) Calibration and Standards.

(k) Safety.

(l) Proficiency Testing (CAP Surveys).

c. DCN/CN will:

(1) Identify all nursing personnel who will perform point of care testing.

(2) Provide overall supervision of nursing personnel who perform point of care testing.

d. Department/Clinic Chief OIC's will:

(1) Serve as the responsible person for all aspects of the POCT program within their respective department /service.

(2) Appoint, in writing, the POCT supervisor for the department/clinic. This individual will manage the POCT in accordance with this policy. Determine the needs of POCT in his/her area and submit requests for additions or deletions of tests from the current authorization, to the 18th MEDCOM Pathology Consultant for consideration.

e. POCT SUPERVISORS will:

(1) Ensure that all personnel identified are properly trained on the performance of all waived tests performed in the section. NOTE: Documentation of all training and competency is required.

(2) Supervisors will provide quarterly training at the POCT sites.

(3) Report the status of POCT to the POCT Coordinator on a monthly basis, in addition, it must also be reported on a monthly basis in the departmental/clinic Quality Improvement (QI) meeting. The report submitted to the POCT Coordinator will be incorporated into the Department of Pathology monthly Performance Improvement Committee Meeting minutes and reported to ECOMS. The details of the required contents for the status report are addressed in the program.

(4) Submit Quality Control (QC) Documentation and patient result reports by the 5th working day of each month to the POCT Coordinator for review. Send a copy of all quarterly in-service conducted, with a by name list of attendees. All documentation must be reviewed by the clinic OIC/Laboratory OIC. Ensure continuous compliance by signing QC documentation on a weekly basis.

(5) As applicable, review all instrument/equipment maintenance data on a weekly basis. Contact Medical Maintenance as necessary for servicing (i.e. timing checks for microhematocrit centrifuges).

4. **GENERAL:**

a. POCT sites must perform all laboratory testing in accordance with the procedural instructions provided in the subsequent appendices to this policy. This is necessary in order to ensure repeatedly reliable results based on accepted scientific practices.

b. REPORTING AND RECORDING RESULTS:

All results obtained using Point of Care Testing (Waived Testing) will be used for screening purposes only.

(1) Critical Values/Panic Values:

(a) Personnel will notify the department or clinic OIC and annotate who they spoke with, date, time, and value on the patient results log.

(b) Submit a phone number that will be accessible for critical values within your department/clinic.

(2) Documentation: Results must be written in the patient's record and on the Patient Results Log sheet. While this may seem redundant, it is important that the performing ward/clinic possess an "audit trail" for all lab testing performed by the staff.

c. LIST OF WAIVED TESTS:

As of 8 July, 1996, the following tests were included in Clinicial Laboratory Improvement Act of 1988 "Waived Tests Category" (the base document for the CLIP).

(1) Urinalysis by dipstick for the following: bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, urobilinogen, and specific gravity.

(2) Urine Pregnancy Tests - visual color comparison test

(3) Erythrocyte sedimentation rate - non automated

(4) Hemoglobin by copper sulfate –method- non automated

(5) Hemoglobin by single analyte instruments

(6) Fecal Occult Blood

(7) Spun microhematocrit

(8) Blood glucose monitoring devices cleared by the Food and Drug Administration (FDA) for home use

(9) One Step Strep A Test (rapid strep)
(10) Provider-performed microscopy

5. **REFERENCES:** Documents identified below will be maintained at the 121st General Hospital, Department of Pathology and in each outlying clinical lab. These documents will be available for review upon request.

a. Accreditation Manual for Hospitals, Joint Commission on Accreditation of Healthcare Organizations, 2000.

b. Inspection Checklist, Limited Services Laboratory, College of American Pathologists (CAP), 2000.

c. Inspection Checklist, Point of Care Testing, College of American Pathologists (CAP), 2000.

d. Department of Defense Clinical Laboratory Improvement Program (DOD CLIP), 1996.

6. GLOSSARY:

a. Point of Care Testing Sites(CAP definition) – Those analytical patient testing activities provided within the institution, but performed outside the physical facilities of the laboratory. The central criterion of POCT is that it does not require permanent space. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g.' capillary blood glucose).

b. Quality Control (QC) – A mechanism, specific for each test, which allows for the periodic confirmation of accuracy and or specificity. Samples possessing known values (quantitative amounts or simply positive/negative) are used to challenge the test procedure currently in use. If the procedure produces results, which are within previously established ranges of acceptability, the subsequent patient results obtained by the method are determined to be acceptable for screening purposes only.

c. Quality Assurance (QA) : A program designed for the continuous monitoring, evaluation and improvement of the overall operation of a facility or function. NOTE: QC is a portion of the POCT overall QA program.

d. Performance Improvement (PI): A program designed to evaluate performance through the investigation of problem(s) inherent in a given system, the implementation of improvements in the system and the measurement of the outcomes of those improvements on the system.

7. The proponent of this policy is the 18th MEDCOM Pathology Consultant.

// Original Signed //
PHILP VOLPE
Colonel, MC
Commanding

2 Annexes
A. Procedure of POCT Quality Assurance
B. POCT Quality Assurance

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